

### REMARKS

In response to the May 19, 2008 Office Action, Applicant submits the following remarks. Currently, claims 1-3, 5-16, and 18-27 are pending in the application with claims 1, 3 and 16 being independent. Claims 1, 3, and 16 have been amended. Support for these amendments can be found at least on page 6, para. [0022] of the present application's specification and FIGS. 3-4. Claims 6 and 19 are amended to correct for antecedent basis. Claim 18 is amended to delete duplicative subject matter. Claims 4 and 17 have been previously cancelled without prejudice or disclaimer. Claims 25, 26 and 27 are new. The support for these claims can be found in Applicant's specification at least in paragraph [0005], among other places.

#### 35 U.S.C. §102

In the May 19, 2008 Office Action, the Examiner rejected claims 1-3, 7, 16 and 20 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,159,211 to Boriani (hereinafter, "Boriani"). Applicant respectfully traverses this rejection.

Amended claim 1 recites, *inter alia*, cage assembly adapted to be implanted in a spinal column for treating degenerative or ruptured discs and replacing damaged vertebral bodies, the assembly includes a rigid cage formed in an annular configuration of a biologically inert material, the cage having opposed upper and lower surfaces extending about perimeter portions thereof, a plurality of raised ridges projecting outwardly from each of the perimeter surfaces for engaging the spinal column and securing the assembly therein and disposed at offset angles with respect to each other, wherein at least one of the perimeter surfaces of the cage defines a plurality of indexing members thereon and wherein the cage assembly includes at least one spacing element adapted to be secured to the one cage for the stacked attachment of the cage with a second cage, the indexing members cooperating with portions of the spacing element for axially aligning the spacing element with the one cage, the spacing element is configured to have flat upper and lower surfaces that do not include the raised ridges and is further configured to be disposed in a spaced arrangement with the cage and the second cage.

In response to the May 19, 2008 Office Action, Applicant incorporates by reference in their entirety and reiterates his arguments submitted in response to the Final Office Action, dated October 26, 2007. Additionally, Applicants submits the following remarks.

As understood by Applicant, Boriani discloses a surgical prosthetic modular device that can be used singularly or stacked together to replace excised vertebral tissue. (Boriani, Abstract). Borian's device includes a rectangular body having a top face and a bottom face along with sidewalls therebetween. (Boriani, Col. 3, lines 33-39). Boriani's top and bottom faces include ridges that run in the anterior/posterior direction and other ridges that run in the medial/lateral direction. The ridges are design to interdigitate to form a stack. (Boriani, FIG. 2, Col. 3, lines 41-46). Thus, Boriani's modular devices cannot be compared to the cage assembly of the present invention, as the former do not include a spacing element configured to have flat upper and lower surfaces that do not include the raised ridges, as recited in claim 1. (emphasis supplied). Instead, each one of top and bottom faces of Boriani's devices includes ridges, as shown in Boriani's FIG. 2. Additionally, in a stacked arrangement, each one of Boriani's devices is configured to be disposed flush against at least one other device, hence, there is no spacing between the devices. (Boriani, FIG. 2). This further supported by Boriani's statement that "ridges ... interdigitate" with one another. (Boriani, Col. 3, lines 45-46). As such, Boriani fails to include a spacing element that is configured to be disposed in a spaced arrangement with the cages, contrary to the recitation of claim 1. Hence, Boriani fails to disclose all elements of claim 1, and does not anticipate it. Applicant respectfully requests allowance of claim 1.

Claims 2-3, 7, 16 and 20 are not anticipated by Boriani for at least the reasons stated above with regard to claim 1. As such, the rejection of claims 2-3, 7, 16 and 20 is respectfully traversed. The Examiner is requested to reconsider and withdraw his rejection of claims 2-3, 7, 16 and 20.

In the May 19, 2008 Office Action, the Examiner rejected claims 3-6, 8-10, 12-16, 18-19, 21 and 23 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Pub. No. 2004/0073314 to White et al. (hereinafter, "White"). Applicant respectfully traverses this rejection.

As understood by Applicant, White discloses a vertebral replacement device for supporting adjacent vertebrae and that includes a vertebral body member having at least one upper or lower disc replacement member engaged thereto at one end thereof. (White, Abstract). White's vertebral replacement device includes a vertebral body member having an upper and lower disc replacement members coupled to the vertebral body member at the top and bottom, respectively. (White, FIGS. 12-14, para. [0083]). The vertebral body member includes end

surfaces that include a concave curvature in at least one direction transverse to longitudinal axis to provide a solid bearing relationship with an adjacent convex surface of the disc replacement members. (White, para. [0083]). As illustrated, in White's FIG. 12, the disc replacement devices are disposed with regard to the vertebral body member in a similar fashion, as compared to the devices in Boriani, i.e., flush against the vertebral body. (White, FIG. 12). This is different than claim 3's recitation of a spacing element that is configured to be disposed in a spaced arrangement with the cages. (emphasis supplied). Further, the top and bottom surfaces of White's vertebral body are curved (i.e., concave), as such they are not flat, contrary to the recitation of claim 3 of a spacing element configured to have flat upper and lower surfaces. (emphasis supplied). Thus, White fails to disclose all elements of claim 3 and thus, does not anticipate it. Applicant respectfully requests allowance of claim 3.

Claims 4-6, 8-10, 12-16, 18-19, 21 and 23 are not anticipated by White for at least the reasons stated above with regard to claim 3. Thus, the rejection of claims 4-6, 8-10, 12-16, 18-19, 21 and 23 is respectfully traversed. The Examiner is requested to reconsider and withdraw the rejection of claims 4-6, 8-10, 12-16, 18-19, 21 and 23.

35 U.S.C. §103

The Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the Examiner does not produce a prima facie case, Applicant is under no obligation to submit evidence of non-obviousness. MPEP §2142. According to MPEP §2143, to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be a reasonable expectation of success. Second, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Finally, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

In the May 19, 2008 Office Action, the Examiner rejected claim 11 under 35 U.S.C. § 103 as being unpatentable over White. Applicant respectfully traverses this rejection.

Applicant respectfully submits that the Examiner has not met his burden in proving a prima facie case of obviousness. As explained above, White fails to disclose all claimed elements, as recited in the amended claim 3. Since claim 11 is dependent on the independent

claim 3, White fails to render claim 11 obvious for at least the reasons stated above with regard claim 3.

In addition to the above reasons, Applicant reiterates and incorporates by reference in their entirety his Arguments submitted in response to the October 26, 2007 Final Office Action.

In May 19, 2008 Office Action, the Examiner admitted that White does not disclose “a pair of resilient members on opposite sides of the spacer element.” (Office Action, page 5). The Examiner further stated that: “mere duplication of essential working parts of a device involves only routine skill in the art (Office Action, page 5).

Claim 11, recites, *inter alia*, “...a second pair of resilient locking members...” (emphasis supplied). White fails to disclose a pair of locking members. Instead, White only discloses engagement members 320, 321, where each includes a projection or engaging portion 352 and a stem 350 connected or integrally formed with end surface 314 of body 312 (White, para. [0089]). Stem 350 has a thickness that allows engaging member 320 to deflect inwardly toward longitudinal axis 302 in response to a force applied to engaging portion 352. (White, para. [0089]). However, nowhere does White disclose that any portion of its vertebral replacement device is a “locking member”, contrary to the recitation of claim 11. Thus, White fails to disclose, teach or suggest all of the claimed elements of claim 11. Thus, this rejection is respectfully traversed. Applicant requests that the Examiner withdraw his rejection of claim 11.

In the May 19, 2008 Office Action, the Examiner has rejected claim 22 under 35 U.S.C. § 103 as being obvious over Boriani in view of U.S. Patent No. 5,192,327 to Brantigan (hereinafter, “Brantigan”). Applicant respectfully traverses this rejection.

Applicant again reiterates and incorporates his prior arguments in their entirety herein by reference. Applicant respectfully submits that the Examiner has not met his burden in proving a prima facie case of obviousness since the Examiner, in part, has not shown that Boriani in view of Brantigan teaches or suggests all of the features of claim 22.

Claim 22 is a dependent claim based on independent claim 16. As such, claim 22 is patentable over Boriani for at least the reasons stated above with regard to claim 16. Brantigan fails to cure the deficiencies of Boriani. As understood by Applicant, Brantigan discloses a surgical prosthetic implant that is used singularly or stacked together to support and fuse together

adjacent vertebrae or to totally or partially replace one or more vertebrae in a vertebral column. (Brantigan, Abstract). Brantigan further includes ridges that are formed longitudinally across the end faces of the implant. (Brantigan, FIG. 1, Col. 4, lines 15-19). The ridges further define peaks and valleys that are configured to allow stocking of one implant on top of the other. (Brantigan, FIGS. 1-5). Thus, Brantigan ridges are parallel to each other. This is different than the present invention, where raised ridges are disposed at offset angles with respect to each other, as recited in claim 16. Further, Brantigan also fails to disclose, teach or suggest that the spacing element is configured to have flat upper and lower surfaces that do not include the raised ridges and is further configured to be disposed in a spaced arrangement with the cage and the second cage, as recited in claim 16. As such, Brantigan fails to disclose all elements of claim 16. Thus, claim 22 is patentable over Boriani, Brantigan or their combination for at least the reasons stated above with regard to claim 16. As such, the rejection of claim 22 is respectfully traversed. The Examiner is requested to reconsider and withdraw his rejection of claim 22.

In the May 19, 2008 Office Action, the Examiner rejected claim 24 under 35 U.S.C. § 103 as being obvious over White in view of Brantigan. Applicant respectfully traverses this rejection.

Claim 24 is dependent on claim 17, which in turn depends on claim 16. Thus, Claim 24 is patentable over White, Brantigan or their combination for at least the reasons stated above with regard to claim 16. Thus, this rejection is respectfully traversed. The Examiner is requested to reconsider and withdraw his rejection of claim 24.

In the May 19, 2008 Office Action, the Examiner rejected claims 1, 3, 16 and 24-27 under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 7,309,358 to Berry (hereinafter, "Berry") in view of Brantigan. Applicant respectfully traverses this rejection.

As understood by Applicants, Berry discloses vertebral body and disc space replacement devices (Berry, Abstract). Berry has a similar structure to White. In fact, both Berry and White are continuation in part based on the same patent application no. 10/103,237. Thus, Berry suffers from the same deficiencies as White. Specifically, Berry discloses a stacked arrangement of disc replacement devices, where such devices are disposed flush against each other. (Berry, FIGS. 24-29, 35). In its other configurations, Berry includes a vertebral body member (similar to White) that is also disposed flush against the disc replacement devices, where the vertebral body

member includes surfaces that are not flat (Berry, FIGS. 12-13). Thus, Berry fails to disclose the spacing element is configured to have flat upper and lower surfaces that do not include the raised ridges and is further configured to be disposed in a spaced arrangement with the cage and the second cage, as recited in claim 1. (emphasis supplied). Instead, Berry's arrangement does not allow any spacing or any flat surfaces on its vertebral body member. As stated above, White suffers from the same drawbacks. Thus, the combination of Berry and White fails to disclose, teach or suggest the spacing element is configured to have flat upper and lower surfaces that do not include the raised ridges and is further configured to be disposed in a spaced arrangement with the cage and the second cage, as recited in claim 1. Thus, neither Berry, White, nor their combination render claim 1 obvious. As such, this rejection is respectfully traversed and Applicant requests allowance of claim 1.

Claims 3, 16, and 24-27 are not rendered obvious by the combination of Berry and White for at least the reasons stated above with regard to claim 3. As such, the rejection of claims 3, 16, and 24-27 is respectfully traversed. The Examiner is requested to reconsider and withdraw his rejection of claims 3, 16, and 24-27.

**Conclusion**

No new matter has been added. The claims currently presented are proper and definite. Allowance is accordingly in order and respectfully requested. However, should the Examiner deem that further clarification of the record is in order, we invite a telephone call to the Applicants' undersigned attorney to expedite further processing of the application to allowance.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (212) 935-3000.

The Commissioner is authorized to charge any fees that may be due to the undersigned's account, Deposit Account No. **50-0311**, Reference No. Reference No. **26786-520-NATL**. Please address all correspondence to Customer Number **35437**.

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Respectfully submitted,



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